

provide management with monitoring tools that will permit real-time in-depth cost analysis, resource allocation, and business forecasting. LIMS provides for sample/specimen life-cycle management (accessioning, bar-coding, tracking, archiving), automatically or manually collecting lab results from instruments in a secure and validated manner, tracking reagent lot numbers and expiration dates, documentation and tracking instrumentation calibration and maintenance activities, and technician training. Most importantly, this system will improve and maintain the quality of clinical study endpoints, laboratory data and processes.

### ***Who will use these systems?***

Any individual involved in a FDA-regulated process that produces regulatory information (records) or documents intended for any FDA-regulated activity. Some examples of these documents include:

- ◆ Data and documents required by FDA regulations, such as clinical study reports, patient record datasets, Investigational New Drugs (INDs), investigator brochures, and annual reports;
- ◆ Records of the development, use or maintenance of information systems that are required to support a regulated project (e.g. clinical trial); and,
- ◆ Data and documents that are submitted to the FDA for their use in regulatory decision-making.

These individuals are located anywhere a TSG-sponsored FDA activity is using a computer system.

### ***Why does USAMRMC need these systems?***

Until now, study information has been captured in unconnected, home-grown databases and large paper-base files. There is no system that currently tracks where all of this data is stored, and it is not readily accessible to make informed decisions. The FDA has specific regulations and requirements that USAMRMC must meet in the systems and management of our information. One of these requirements, the Title 21 Code of Federal Regulations (CFR), Part 11, can be thought of as an "umbrella" that covers the computer systems, data, and signature requirements of the Good Laboratory Practices (GLPs) and Good Clinical Practices (GCPs), when the data and signatures are in electronic form. The GLP, GCP, and Good Manufacturing Practice (GMP) regulations, and other FDA regulations that provide the systems, records and signature requirements, are called "Predicate Rules." Overall, the FDA expects USAMRMC to provide trustworthy data; accurate and complete records and reports; reliable systems and processes; secure data, systems and facilities; as well as qualified and trained personnel when utilizing computerized records. This compliance is required when FDA regulated records are created, modified, maintained, archived, retrieved, or transmitted in electronic form, or are electronically signed or submitted to the FDA. In addition, USAMRMC also needs these systems to attract and work with CRDA partners, who use the industry best practices, which will improve the quality and credibility of our scientific data. Overall, these systems will improve business processes across USAMRMC

by providing data integrity, security, access, and speed.



***Protect, Project, Sustain***

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# **MeRITS**

# **PMO**

## **General Information**

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## **FAQs**



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# **MeRITS PMO**

## ***What is the MeRITS Project?***

The Medical Research Information Technology System (MeRITS) Project was officially charted by Major General (MG) John Parker on 19 November 2001, as a permanent Project Management Office within the Headquarters of USAMRMC. The MeRITS Project Manager reports to the Commanding General (CG), the Milestone Decision Authority, through the Principal for Acquisition.

The project will consist of various commercially available software packages that ensure secure, reliable, and available information. The systems also will be integrated to enable meaningful search, analysis, review, and submission of regulated information to the FDA.

## ***MeRITS PMO Mission***

The mission of the MeRITS PMO is to provide investigators, management and support staff with regulatory-compliant and practical information management tools and efficient, standardized business processes, which are necessary to effectively implement those tools, to assist in the development of FDA-regulated drugs, vaccines, biologics, and devices for military personnel.

## ***MeRITS PMO Vision***

Our vision is a system of sufficient, trained people; efficient and standardized business

processes; and validated information management technology, working together to develop drugs, vaccines and devices that are attractive to prospective co-development partners, are readily approved by the FDA, and improve the health of military personnel.

## ***MeRITS PMO Goals***

- ◆ Identify Command needs for electronic storage, sharing, searching, analysis, reporting, monitoring and submission of FDA-regulated data and documents;
- ◆ Identify, validate and implement research information systems and services that meet the Command's requirements, and foster improvements in the planning and conduct of medical research and development activities leading to the highest quality FDA regulatory submissions;
- ◆ Improve data flow between USAMRMC organizations, commercial partners and the FDA;
- ◆ Improve Command compliance with FDA regulations; and,
- ◆ Improve business efficiencies of FDA-regulated product development.

To accomplish these goals, MeRITS will provide the means for electronic:

- ◆ Data capture from pre-clinical and clinical studies for easier access and analysis by investigators and support staff;
- ◆ Management of data and documents within the Command and sharing with our industry partners;
- ◆ Submission of data and regulatory files to the FDA; and,
- ◆ Compliance with federal regulations.



## ***Individual Projects***

The **Electronic Document Management System (EDMS)**, branded FRED for FDA Regulated Electronic Documents, is focused on the reduction, and possibly the elimination of paper-based systems for regulatory data, documents and records. This regulated data includes standing operating procedures (SOPs), policies, guidelines, investigational new drugs files (INDs), protocols, clinical study documentation, study reports, FDA correspondence, and much more. The FRED end users will be able to browse and navigate regulatory content, search for and retrieve information, as well as read, review, print and/or download the most current versions of documents. In addition, end users will be able to add new versions and produce audit reports for each document. Most importantly, FRED will enable the Command to streamline processes and mitigate risks through the use of a collaborative, secure information environment.

The **Clinical Data Process and System (CDPS)** Project is focused on the improvement of the effectiveness, efficiency, and regulatory compliance of clinical data management (CDM) and clinical statistical processes, standards, and systems within USAMRMC. Improvements in these areas will provide for high quality data and support compliance with the FDA regulations, and enhance the Command's ability to develop and deliver the best medical solutions.

The **Laboratory Information Management System (LIMS)** Project is focused on improving laboratory practices across USAMRMC. To improve these practices, this system will